

## REMARKS

Claims 33-82 are pending in the present application. Claims 41-53, 62-72 and 79-82 have been withdrawn from consideration, leaving Claims 33-40, 54-61 and 73-78 for consideration upon entry of the present Amendment.

Reconsideration and allowance of the claims is respectfully requested in view of the following remarks.

### Non-compliance with Requirements for Patent Applications Containing Nucleotide Sequence

A Notice regarding a "melted" sequence listing diskette was received on April 4, 2003. A replacement diskette and paper copy of the sequence listing along with the Statement verifying identical computer readable and paper copy were mailed on April 9, 2003. A return postcard was received by Cantor Colburn LLP from the PTO on April 14, 2003. As the Office Action is dated May 5, 2003, more than two weeks after the sequence listing was received by the PTO, Applicants are unclear as to why the Examiner did not have the replacement sequence listing. A second replacement DNA sequence listing is being submitted herewith.

### Claim Objections

Claim 79 stands objected to for a typographical error (*an or* EDG-1). This typographical error was corrected in the Amendment dated January 21, 2003.

### Claim Rejections Under 35 U.S.C. § 112, First Paragraph

Claims 33-40, 54-61, and 73-78 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in relevant art that the inventors, at the time the applications was filed, had possession of the claimed invention. Applicants

In making the rejection, the Examiner states :

Claims 33, 34, 36-40, 54, 55, 57-61, 73, and 76-78, drawn to antisense to any human EDG-1 and EDG-3 gene target, are not supported for written description purposes since the specification as filed does not provide the actual nucleic acid sequences for human EDG-1 and EDG-3 which is "essential matter" to the claimed invention for the design of antisense to these sequences.

(Paper 26, Page 4)

The Examiner goes on to point out MPEP 608.01(p) which defines "essential material" as "that which is necessary to (1) describe the claimed invention and (2) provide an enabling disclosure of the claimed invention" (Paper 26, Page 4). Regarding an antisense oligonucleotide invention, the Examiner alleges that "the EDG-1 and EDG-3 gene sequences is considered essential material to the claimed invention" (Paper 26, Page 5). The Examiner states that "Applicant has not provided any specific reference to the human EDG-1 or EDG-3 target gene sequences" (Paper 26, page 5).

In the previous response filed on January 21, 2003, Applicants supplied an updated DNA sequence listing that included the sequences for human EDG-1 and EDG-3 as they were known in the art at the time the invention was made. Applicants also amended the Specification to include SEQ ID NOs. for the added sequences. As stated above, Applicants received a notice that the diskette mailed on January 21, 2003 had been melted, and a new diskette, paper copy and statement were mailed on April 9, 2003. The Specification was amended in the January 21, 2003 response to contain specific reference to the nucleotide sequences for EDG-1 and EDG-3.

Applicants maintain that the addition of the sequences for human EDG-1 and EDG-3 is not new matter because, as is clearly described in the background section of the present Specification, the human EDG-1, human EDG-3 gene sequences, and other EDG gene sequences were known in the art (see Page 3, lines 12-19). The human EDG-1 and

Applicants submit that because the human EDG-1 and EDG-3 gene sequences were known in the art, one of ordinary skill in the molecular

biology arts would know what the target sequences were based on the name of the gene. It is within the ordinary skill of the artisan to obtain the nucleotide sequence from the name of a gene and the species of the organism, using a public database such as the NCBI database. In doing such a search using human EDG-1 as a keyword, for example, one of skill in the art would readily obtain accession number NM\_001400 as the Applicants did in preparing their response of May 14, 2002. Similarly, searching human EDG-3 would result in accession number NM\_005226.

The human EDG-1 gene sequence was published by Hla and Maciag in the Journal of Biological Chemistry **265**, 9308-9313 (1990). Other references for the human EDG-1 gene sequence include An et al., FEBS Letters **417**, 279-282 (1987) and Lee et al., Science **279**, 1552-1555 (1998). All three references are cited in Accession number NM\_001400. Applicants submit that based on the foregoing references, the human EDG-1 gene sequence was well known in the art at the time of the invention. There was only one publicly available sequence for human EDG-1 at the time the invention was made.

The human EDG-3 gene sequence was published in Yamaguchi et al. in Biochem. Biophys. Res. Commun. **227**, 608-614 (1996). Other references disclosing the human EDG-3 gene sequence include An et al., FEBS Letters **417**, 279-282 (1987) and Ancellin and Hla, Journal of Biological Chemistry **274**, 18997-19002 (1999). All three references are cited in Accession number NM\_005226. Applicants submit that, based on the foregoing references, the human EDG-3 gene sequence was well known in the art at the time of the invention. There was only one publicly available sequence for human EDG-3 at the time the invention was made.

On Paper 26, Page 6, the Examiner reproduced the section of MPEP 2163 regarding analysis of the claimed invention at the time the invention was made in view of the teachings of the specification and the level of skill in the art at the time the invention was made. The Examiner then states that "one of skill in the art would not have known what the target gene sequences constituting "EDG1" or "EDG3" were from the disclosure

one of ordinary skill in the art would know which DNA sequences were being described.

The sequences of the human EDG-1 and EDG-3 genes were readily available in public

databases which are searchable by the gene name. Applicants previously made reference to the Lee reference (Lee, et al. Cell 99, 301-312, 1999), which was incorporated by reference in the present Application as filed, and clearly references the human EDG-1 and EDG-3 sequences as they are now incorporated into the Specification. The names human EDG-1 and EDG-3 clearly identify the gene sequences for one of ordinary skill in the art.

The Specification now contains the DNA sequence listings for the EDG-1 and EDG-3 genes and thus contains sufficient disclosure to enable one of ordinary skill in the art to practice the claimed invention as is required under 35 U.S.C. § 112. Based on the nucleotide sequences of human EDG-1 and EDG-3, one could readily design an antisense oligonucleotide according to the present claims. For at least the foregoing reasons, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph, are requested.

Allowable Subject Matter

Applicants wish to thank the Examiner for pointing out the patentability of claims directed to SEQ ID NOs:1, 2 and 5 if such claims use "is" or "consisting of" language. Given the foregoing arguments, Applicants elect to not amend the claims as suggested at this time.

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance is requested.

Docket No. UCT-0012  
(Client docket #) 99-027

If there are any additional charges with respect to this Amendment or otherwise,  
please charge them to Deposit Account No. 06-1130 maintained by Cantor Colburn LLP.

Respectfully submitted,

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